IN THE UNITED STATES PATENT AND TRADEMARK OFFICE

In re application of:

WARREN WARD

Group Art Unit: 1595

Examiner: Tigabu Kassa

Serial No.: 10/595,033

Filed: January 4, 2006

For: COMPOSITIONS COMPRISING COMPONENTS COATED WITH A LIQUID IMPERMEABLE BUT GAS PERMEABLE LAYER, USE THEREOF FOR TREATING CUTANEOUS AND OTHER EXOCRINE GLAND DISEASES

Attorney Docket No.: WAW 0101 PUSA

PRE-APPEAL BRIEF REQUEST FOR REVIEW

Commissioner for Patents
U.S. Patent & Trademark Office
P.O. Box 1450
Alexandria, VA 22313-1450

Sir:

Applicant hereby requests review of the legal and factual basis of the final rejections prior to the filing of an Appeal Brief.

No amendments are being filed with this request.

This request is being filed concurrently with a Notice of Appeal and applicable fees.

The review is requested for the reasons stated on the attached sheets of no more than five (5) pages.

REMARKS

Status of the Claims

At the time of the final Office Action dated June 23, 2010, claims 1-28, 30-34, and 36-37 were pending; claims 1-6, 12-23, and 34 were withdrawn from consideration; claims 7-11, 24-28, 30-33, and 36-37 were considered and rejected. Particularly, claims were rejected under 35 U.S.C. § 101; claims 7-11, 24-28, 30-33, and 36-37 were rejected under 35 U.S.C. § 112, first paragraph, as lacking enablement, and second paragraph, as being indefinite.

Independent Claim 24

Independent claim 24 recites a preparation for use as a medicament, comprising a medically efficacious substance coated with an aqueous liquid impermeable but gas permeable layer for surrounding and preventing release of the medically efficacious substance, wherein the layer contains a ceramic, a clay, an inorganic non-metallic material, a polymer, a natural wax, a perforated stainless steel, or beeswax hardened with cornstarch and talc. Claims 7-11, 25-28, 30-33 and 36-37 depend from claim 24.

Claim Rejection under 35 U.S.C. § 101

As stated on page 2 of the final Office Action, claims stand rejected under 35 U.S.C. § 101. For at least the reasons set forth below, Applicant respectfully traverses this rejection.

MPEP § 2107.02 (IV) in relevant portion provides that, to properly reject a claimed invention under 35 U.S.C. § 101, the Office **must** (a) make a *prima facie* showing that the claimed invention lacks utility, **and** (a) provide a sufficient evidentiary basis for factual assumptions relied upon in establishing the *prima facie* showing. Accordingly, the Office **must** do more than merely question operability - it **must** set forth factual reasons which would lead one skilled in the art to question the objective truth of the statement of operability. The *prima facie* showing **must** contain the following elements: 1) an explanation that clearly sets forth the reasoning used in concluding that the asserted utility for the claimed invention is neither both specific and substantial nor well-established; 2) support for factual findings relied upon in reaching this conclusion; and 3) an evaluation of all relevant evidence of record, including utilities taught in the closest prior art. It is **imperative** that Office personnel use specificity in

setting forth an initial rejection under 35 U.S.C. § 101 and support any factual conclusions made in the *prima facie* showing. Moreover, an applicant's assertion of utility creates a **presumption of utility** that will be sufficient to satisfy the utility requirement of 35 U.S.C. 101.[1] Where an applicant has specifically asserted that an invention has a particular utility, that assertion **cannot** simply be dismissed by Office personnel as being "wrong."[2]

In making and maintaining this lack of utility rejection, the Examiner provides a single paragraph of 73 words (reproduced below) as reasons for supporting the rejection.

> The claimed invention lacks patentable utility. The instant application fails to provide adequate evidence to support the utility of the invention. Specifically, there is insufficient evidence to show that a compound which is not released on or into the body can have any medically beneficial effect. Additionally, the agents used to form the liquid impermeable but gas permeable layer (e.g. wax) are also used in the art to form controlled release formulations of drugs.

As can be seen from the above reproduced paragraph, the Examiner sets forth the rejection with a conclusory first sentence of lack of utility, follows with a conclusory second sentence of lack of adequate evidence for supporting the utility. In so doing, the Examiner **impermissibly** makes and maintains the rejection without meeting the required burden pursuant to relevant portions of MPEP cited above, namely, showing clear explanation for the lack of utility assertion, providing factual findings and support thereof, and providing an evaluation of all relevant evidence of record. Therefore, the Examiner has **not** properly established a lack of utility rejection under 35 U.S.C. § 101 in view of requirements and obligations set forth in relevant MPEP provisions cited above.

Moreover, the Examiner has **impermissibly** not been receptive to Applicant's express assertion of utility, which is presumed as meeting the utility requirement, nor to arguments and evidence Applicant has submitted for the record thus far. For instance, Applicant has stated that the claimed invention is useful for reducing symptoms of and/or for treating disorders associated with medical conditions characterized by blockage of exocrine glands including ducts of sweat glands. *See* paragraphs [0016] and [0017] of Applicant's original application.

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[1] *See* MPEP2107.02(I).

[2] *See* MPEP 2107.02 (III) (B).

In maintaining the rejection, notwithstanding the above, the Examiner continues to **impermissibly** assert disbelief as to the utility of the claimed invention, and continues to **impermissibly** mis-characterize the claimed invention. In particular, the Examiner keeps asserting that the claimed invention must be released or must bind to a receptor for any *in vivo* activities.[3] Just as acknowledged by the Examiner[4] that an invention does **not** have to be a drug to have utility, an invention, such as Applicant's claimed invention, does **not** have to be released or bind with body cell receptors to be useful.

As stated herein above, Applicant is not required to provide mechanisms of action as to how his/her invention works. However, Applicant has provided in the original description his best understanding, at the time of the invention, in explaining how the invention would work. Further, and to this end, Applicant has proposed several mechanisms in response to Examiner's continuing disbelief as to how the claimed invention operates. For instance, Applicant has proposed that when placed near to or against one's skin or placed intact in one's body, the claimed preparation can be in communication with the skin via gases in the surrounding environment. Warren Ward's Declaration of April 07, 2009 (hereinafter "the Ward Declaration"), at paragraphs 9 and 10. Moreover, EquiwinnerTM patches according to one or more embodiments of the claimed invention have been widely accepted in many countries and well received in the horse trainers community. *See* paragraphs 17 and 18 of the Ward Declaration. The Examiner further opines[5] that the Ward Declaration is not sufficient for establishing the utility because, according to the Examiner, recitation of commercial success is irrelevant for overcoming a lack of utility rejection. Applicant respectfully requests that Examiner provide support for this assertion. To the contrary, the Examiner's attention is respectfully directed to MPEP § 2107.02 (VI), which in relevant portion provides that an applicant **can** rebut a lack of utility rejection using **any** combination of the following: amendments to the claims, arguments or reasoning, or new evidence submitted in an affidavit or declaration under 37 C.F.R. § 1.132, or in a printed publication.

Moreover, and contrary to the Examiner's assertion, there are known substances

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[3] *See* page 3 of the instant Office Action.

[4] *See* page 3 of the Office Action dated October 5, 2009.

[5] *See* page 5 of the Office Action dated October 5, 2009.

capable of exerting *in vivo* activities independently of any receptor binding mechanisms. Examples of these substances can readily be found in Applicant's original specification. For instance, metformin as referenced in Example 2 of the Applicant's original specification influences the insulin receptors, however, there is no suggestion anywhere in current literature that metformin binds to insulin receptors. *See* also Li et al., submitted as Exhibit 4B via Applicant's Amendment dated April 5, 2010, states on page 59 that metformin impacts on insulin stimulation via intermediary molecular messengers but not directly on any cellular receptors. *See* also Goodmans as Exhibit 4A submitted via Applicant's Amendment dated April 5, 2010, which states at page 1705 paragraph 3 that metformin "is excreted unchanged in the urine". Metformin cannot both bind to receptors and be excreted unchanged in the urine. Like metformin, capsaicin as referenced in Example 1 of Applicant's original specification is another example of substances that do not function by binding to a receptor. *See* for instance Smart et al., submitted as Exhibit 4C via Applicant's Amendment dated April 5, 2010, states at page 229 that capsaicin is well known to influence but not bind to the vanilloid receptor (VR1). The Examiner **must** use specificity in evaluating these factual findings.

Claim Rejections Under 35 U.S.C. § 112

Claims 7-11, 24-28, 30-33, and 36-37 stand rejected under 35 U.S.C. § 112, first paragraph for lacking enablement, and second paragraph, for being indefinite. *See* pages 5-9 of the final Office Action. This rejection is essentially based on the above-referenced Examiner's assertion that a drug not released is effective in producing any medical effect.[6] Applicant respectfully traverses this rejection for at least the reasons set forth above and further wishes to state the following.

As stated in paragraphs 21 to 32 of the Ward Declaration, sodium chloride as enclosed within the liquid impermeable but gas permeable layer, constructed according to one or more embodiments of the claimed invention, does affect its immediate surrounding environment without the preparation of the invention being changed in any way. The effect on the surrounding metals is solely the result of the construction of the spheres is demonstrated by the observation that a similar amount of sodium chloride to that included in the spheres and

[6] *See* pages 5-6 of the instant final Office Action, page 5 of the Office Action dated October 5, 2009, and page 5 of the Office Action dated June 24, 2009.

cylinders, when dissolved in water has no corrosive effect on the metals. It should be noted that the same two spheres containing coated sodium chloride were used for periods of 48 hours then 48 hours then 24 hours in water without being changed in any way. It should additionally be noted that if the sodium chloride had escaped from the coating this could not be responsible for the action on the metals, only the sodium chloride within the layer had that action. Also if the sodium chloride had escaped from the coating then both the spheres and the cylinders would have floated away from the metal in each case. This did not happen as stated herein above. The tests further support the asserted notion that water molecules are adjacent to the medically efficacious substance through the gas permeable liquid impermeable coating.

Conclusion

For the reasons given above, Applicant respectfully requests that the panel members review the rejections in this application and find that the application is not in condition for appeal. The Commissioner is hereby authorized to charge any additional fees or credit any overpayments as a result of the filing of this paper to Deposit Account No. 02-3978.

Respectfully submitted,

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